UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JAMES J. NIZZO and VIRGINIA C. NIZZO, As Joint Tenants, and CARLO CILIBERTI, On Behalf of Themselves And All Others Similarly Situated,

Plaintiffs,

v.

BIOPURE CORPORATION, THOMAS A. MOORE, CARL W. RAUSCH, and RONALD F. RICHARDS,

Defendants.

CIVIL ACTION No.

04-10065NG

MAGISTRATE JUDGE

CLASS ACTION COMPLAINT
FOR VIOLATIONS OF FEDERAL SECURITIES LAWS
and
DEMAND FOR JURY TRIAL

Plaintiffs have alleged the following based upon the investigation of plaintiffs' counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by Biopure Corporation ("Biopure" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company, and plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein

after a reasonable opportunity for discovery.

Nature of the Action

1. This is a federal class action on behalf of purchasers of the securities of Biopure between March 17, 2003, and December 24, 2003, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

Jurisdiction and Venue

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission ("SEC") [17 C.F.R. § 240.10b-5].

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

4. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Biopure maintains its principal place of business in this District and many of the acts and practices complained of herein occurred in substantial part in this District.

5. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the

means and instrumentalities of interstate commerce, including, but not limited to, mails, interstate telephone communications and the facilities of the national securities markets.

Parties

6. Plaintiffs James J. Nizzo and Virginia C. Nizzo, Joint Tenants, as set forth in the accompanying certification, incorporated by reference herein, purchased the securities of Biopure during the Class Period and have been damaged thereby.

7. Plaintiff Carlo Ciliberti, as set forth in the accompanying certification, incorporated by reference herein, purchased the securities of Biopure during the Class Period and has been damaged thereby.

8. Defendant Biopure develops, manufactures and markets oxygen therapeutics, for both humans and veterinary use, designed to serve as an alternative to red blood cell transfusions and for use in the treatment of other critical care conditions. The Company's principal executive offices are located at 11 Hurley Street, Cambridge, Massachusetts.

9. Defendant Thomas A. Moore ("Moore"), at all times relevant to this action, served as the Company's President and Chief Executive Officer.

10. Defendant Carl W. Rausch ("Rausch"), at all times relevant to this action, served as the Company's Vice Chairman and Chief Technology Officer.

11. Defendant Ronald F. Richards ("Richards") at all times relevant to this action, served as the Company's Chief Financial Officer.

12. The defendants referenced above in ¶¶ 9-11 are referred to herein as the "Individual Defendants."

13. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

14. It is appropriate to treat the Individual Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information

conveyed in the Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly defined group of defendants identified above. Each of the above officers of Biopure, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein. Said defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of federal securities laws.

15. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was traded on the NASDAQ National Market (the "NASDAQ"), and governed by the provisions of the federal securities

laws, the Individual Defendants each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

16. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with Biopure, each of the Individual Defendants had access to the adverse undisclosed information about Biopure's

business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Biopure and its business issued or adopted by the Company materially false and misleading.

17. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

18. Each defendant is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Biopure common stock by

disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (a) deceived the investing public regarding Biopure's business, operations, management and the intrinsic value of Biopure common stock; (b) allowed the Company to sell its common shares generating more than $36 million in proceeds (c) enabled the Individual Defendants and other insiders to sell more than $1.6 million worth of their personally-held shares of Biopure common stock at artificially inflated prices; and (d) caused plaintiffs and other members of the Class to purchase Biopure securities at artificially inflated prices.

Plaintiffs' Class Action Allegations

19. Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. Pro. 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Biopure between March 17, 2003 and December 26, 2003, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a

controlling interest.

20. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Biopure common shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Biopure or its transfer agent and maybe notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

21. Plaintiffs claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

22. Plaintiffs will fairly and adequately protect the interests of the Class members and has retained counsel competent and experienced in class and securities litigation.

23. Common questions of law and fact exist as to all members of the Class and predominate over any questions

solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Biopure; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

24. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

Substantive Allegations

Background Facts

25. Biopure purportedly develops, manufactures and markets oxygen therapeutics, for both humans and

veterinary use, designed to serve as an alternative to red blood cell transfusions and for use in the treatment of other critical care conditions. The Company has developed and manufactures two products: Hemopure - hemoglobin glutamer – 250 (bovine), or HBOC-201-for human use, and Oxyglobin - hemoglobin glutamer – 200 (bovine), or HBOC-301- for veterinary use. On July 31, 2002, Biopure submitted a biologic license application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to market Hemopure in the United States for patients undergoing orthopedic surgery. Previously the Company had obtained approval in South Africa to market Hemopure for the treatment of adult surgical patients who are acutely anemic. In September 2002, the Company received a grant from the U.S. Department of the Army for the purpose of conducting clinical trials of Hemopure for the treatment of certain trauma patients. According to the Company's fiscal 2002 10-K, "[t]he Company has identified trauma as its next clinical development priority and is working with a committee of independent civilian and military trauma experts to broaden its trauma program."

26. Unknown to shareholders, in March 2003, the Company submitted a "trauma study protocol" to the FDA, in

connection with the Company's plans to conduct a "[p]hase II clinical trial" of Hemopure for the treatment of trauma patients. Immediately thereafter, the FDA informed defendants that the proposed clinical trials could not go forward, citing "safety concerns" arising from adverse clinical data submitted as part of the Company's July 2002 BLA seeking FDA approval to market Hemopure to orthopedic surgery patients. Importantly, this also put defendants on notice that FDA approval of the BLA, which would allow the first commercial distribution of Hemopure in the United States, was in serious doubt and most certainly would be delayed beyond the time frames previously communicated by defendants to the investing public. Over the next nine months, despite numerous opportunities in press releases, analyst conference calls and SEC filings, defendants failed to disclose any of these adverse facts to the investing public. Indeed, the Company's periodic comments regarding Hemopure during the Class Period, materially misled investors concerning the commercial viability of Hemopure and the expected commencement of marketing the product in the U.S. Prior to the disclosure of these adverse facts, defendants conducted at least two offerings of Biopure common stock generating millions of dollars in proceeds and

certain high-level Biopure insiders, including defendants Moore and Rausch, sold hundreds of thousands of Biopure common shares to the unsuspecting investing public at artificially inflated prices.

27. Then, on December 24,2003, under the threat of civil litigation by the SEC, defendants stunned the market by announcing that, in fact, the FDA had halted further clinical trials of Hemopure due to safety concerns. Defendants also disclosed that the commercial release of Hemopure in the United States would be delayed beyond mid-2004.

28. Market reaction to defendants belated disclosures was swift and severe. On December 26, 2003, Biopure common shares lost over 16% of their value to close at $2.43 per share, representing a decline of more than 239% from a Class Period high of $8.25 per share, reached on or about August 21,2003.

Materially False and Misleading Statements Issued During The Class Period

29. The Class Period begins on March 17, 2003. On that date, Biopure filed its quarterly report on Form 10-Q for the period ending January 31,2003. The Form 10-Q, signed by defendant Richards reported that the Company had

a net loss of $0.36 per share during the first quarter fiscal 2003 compared to a net loss of $0.38 for the same period last year. In addition the Form 10-Q included the following representations concerning the Company's Hemopure research and development efforts, stating in pertinent part as follows:

> Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation. These BLA support costs were $2,232,000 for the first fiscal quarter of 2003 and are expected to continue at approximately the same level **until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA.**
>
> * * *
>
> **If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure, the timing of the construction of additional capacity and other factors that may affect our ability to generate a profit from our research and development of Hemopure. [Emphasis added.]

30. On or about March 25, 2003, Biopure issued a press release announcing that it has raised $13.4 million

in gross proceeds through the sale of 5,548,480 shares of its common stock at $2.42 per share. The press release stated in pertinent part as follows:

> Hemopure® [hemoglobin glutamer - 250 (bovine)] is approved in South Africa for the treatment of adult surgical patients who are acutely anemic and for the purpose of eliminating or reducing the need for allogenic red blood cell transfusion in these patients. Biopure's application to market Hemopure in the United States for a similar indication in adult patients undergoing elective orthopedic surgery is currently being reviewed by the U.S. Food and Drug Administration[.. .]
>
> * * *
>
> The previously announced $4.9 million in FY02/03 Congressional appropriations administered through the U.S. Army and anticipated $4 million in U.S. Navy funding from a Cooperative Research and Development Agreement (CRADA) **for clinical trials of Hemopure in trauma** are project-specific funds independent from Biopure's reported cash on hand. Completion of the pivotal RESUS clinical trial of Hemopure in trauma is contingent upon further funding. $908,900 of the Army funding is from Grant DAMD17-02-1-0697, for which the U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. [Emphasis added.]

31. On or about May 22,2003, Biopure issued a press release announcing its financial results for the second fiscal quarter ended April 30,2003. For the quarter, the company reported a net loss of $0.35 per common share,

compared with a net loss of $0.49 per common share for the corresponding period in 2002. Regarding the FDA's pending approval of Bipoure's Hemopure BLA, the press release stated in pertinent part:

> Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery. As part of this review, the agency has inspected the company's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA to date.

32. On or about May 30, 2003, the Company issued a press release announcing that the FDA had notified Biopure that it will complete its review and act on the Company's BLA for Hemopure by August 29, 2003. Defendant Moore commented on the FDA's review process:

> We're very pleased with the FDA's progress in reviewing our application[.] We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval.

33. On or about July 23, 2003, Biopure issued a press release announcing that it has raised $17.2 million

in gross proceeds through the sale of 3,083,000 shares of its common stock at $5.58 per share.

34. On or about August 21, 2003, Biopure issued a press release announcing its financial results for the third fiscal quarter ended July 31, 2003. For the quarter, the Company reported a net loss of $0.28 per common share, compared with a net loss of $0.43 per common share, for the corresponding period in 2002. The press release included the following representations concerning the FDA's review of the Company's Hemopure BLA, stating in pertinent part as follows:

> On July 30th, the FDA sent Biopure a letter stating that the agency has completed its review of the company s BLA to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials.

35. On or about October 30, 2003, Biopure announced its plan to respond by June 30, 2004, to the FDA's questions regarding its BLA for Hemopure. The press release stated that the Company had adjusted its operating plan to reduce expenses and conserve cash while it completed its written response to the FDA. The press

release stated in pertinent part as follows:

> During the past two months the company has had several substantive interactions with the FDA to clarify the Agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.

Defendant Moore commented, in pertinent part, as follows:

> In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions[.] We view the Agency's questions as a "roadmap" to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible.

36. The statements referenced above in ¶¶ 29-32 and 34-35 were each materially false and misleading when made because they failed to disclose certain existing material facts, including, inter alia:

(a) that Biopure had been notified by the FDA, as early as March/April 2003 that the Company's clinical trials of Hemopure for trauma applications had been put on hold due to "safety concerns" arising from adverse clinical data reviewed by the FDA in connection with the Company's BLA for Hemopure orthopedic

applications;

(b) that FDA approval of Biopure's BLA for commercial marketing of Hemopure in the United States was in serious doubt, and in any event could not have occurred sooner than late 2004; and

(c) based on the foregoing, defendants' opinions, projections and forecasts concerning the Company and its operations were lacking in a reasonable basis at all times.

The Truth Is Revealed

37. On December 24, 2003, after the close of the market, Biopure issued a press release announcing that on December 22, 2003, it received a "Wells Notice" from the staff of the (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the Company relating to defendant's disclosures concerning its communications with the FDA about a trauma study protocol the company submitted to the Agency in March 2003 and about the Company's BLA for Hemopure. The press release stated in pertinent part as follows:

> Biopure submitted the trauma protocol for a Phase H clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in

> the hospital setting, where red blood cell transfusions are available. The FDA placed this trauma protocol under a new IND that is separate from the company's previous IND and its BLA to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The protocol sought to administer up to 15 units of Hemopure, a proposed dosage that was 50 percent higher than administered in previous clinical trials.
>
> After the in-hospital trauma protocol was submitted to the FDA and the new IND was assigned, the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase in orthopedic surgery trial, which was submitted in the BLA. The data from that Phase HI trial has been previously presented at medical meetings.
>
> In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003. The Agency also requested three additional pre-clinical animal studies of Hemopure in conscious swine to address its concerns regarding high-volume administration. After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30,2003.

The press release also indicated that regulatory approval of the Hemopure BLA would be postponed at least until the second-half of calendar 2004: